



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

g1831d

September 27, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-58-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edwin T. Seibold, President
Mrs. Seibold's Bakery, Inc.
2241 Madison Avenue
Granite City, IL 62040

Dear Mr. Seibold:

The Food and Drug Administration (FDA) conducted an inspection of your bakery on August 13, 14 and 16, 2001, during which numerous insanitary conditions were documented. At the conclusion of the inspection, you were issued a Form FDA 483, Inspectional Observations, listing objectionable conditions observed by our investigator in your plant during the inspection. (A copy of the FDA 483 is enclosed.) Samples of rodent evidence from products and from production and storage areas were also collected for analysis as a part of the inspection.

The insanitary conditions observed at your firm during our inspection cause products you manufacture, store and distribute to be adulterated, within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been prepared, packed, or held under conditions whereby they may have become contaminated with rodent, cockroach and fly filth. In addition, insanitary conditions documented within your raw materials render these materials adulterated under Section 402(a)(3) of the Act. They are adulterated under this Section of the Act, in that they consist in whole or in part of filthy substances, including rodent fecal pellets and rodent gnawing through container material into product.

Specifically, the inspection disclosed the following insanitary conditions:

RODENT ACTIVITY

- Three live mice were seen running in the dry-goods storage area, and one live mouse was seen in the northwest corner of the production area.
- Twelve dead mice were found on the floor and under storage flats/racks in the dry-goods storage area.

- A bag of Puratos [REDACTED] bread base in the dry-goods storage area contained a rodent-gnawed hole that penetrated to product. The bag was also stained with rodent urine.
- Approximately twenty rodent fecal pellets were found on piecrust shells and sweet dough on trays in the walk-in cooler.
- Three bags of [REDACTED] White Spray Pastry Flour in the dry-goods storage area contained rodent fecal pellets on the bag surface.
- Three bags of [REDACTED] Flour in the dry-goods storage area contained a rodent fecal pellet(s) on the surface, and one of these bags also contained a rodent urine stain.
- Hundreds of rodent fecal pellets were noted in the dry-goods storage area on the floor under and on product-storage flats.
- Hundreds of rodent fecal pellets were noted in the southeast and southwest corners of the walk-in cooler on product-storage flats. Approximately fifty pellets were also noted on the floor in these areas.
- Approximately 10 rodent fecal pellets were found on the floor under air ducts in the southeast corner of the order prep room.

COCKROACH ACTIVITY

- Approximately 15 live cockroaches were observed inside the bulk flour storage bin in the southwest section of the mix/work area. One live cockroach was seen inside an open bag of [REDACTED] Flour stored in the middle of the bin.
- Approximately 10 live cockroaches, including adults and nymphs, were noted in gaps between damaged/loose wall tiles on the north wall between the freezer and wall sink.
- Approximately 25 live cockroaches were found along a pipe between the water cooler and sink, along the north wall of the mix/work area.
- Live cockroaches were also noted inside the mixer control panel box in the southwest section of the mix/work area, in gaps between damaged/loose wall tiles on the mid-south wall of the work area, and inside the proof box.

- A live cockroach was seen on the exterior of an ingredient bin stored under the main worktable, and on the floor of the walk-in cooler.

FLY ACTIVITY

- Eight live flies were noted in the northeast section of the cake-decorating/entrance area.
- Nine live flies were seen on an electrical cord from the bread dough sheeter to a ceiling outlet over the main worktable.
- Hundreds of flies were observed in and around the exterior dumpster and garbage container located approximately fifteen feet from the northwest exterior walk-in door.

BUILDING and EQUIPMENT DEFICIENCIES

- Accumulations of filth and product residues were noted on processing equipment, including work tables, dividers, sheeters, control panel boxes, the pan washer/pit and the proofer. Filth and product residues were also observed on storage racks and flats, and on floors, walls and ceilings.
- The concrete floor in the pan washer area is pitted and uneven, resulting in stagnant, standing water.
- Tiled walls in the mixing/work area are in disrepair.
- Exterior doors in need of repair, and with gaps underneath, were noted in various areas, including the northeast employee entrance door, the northwest walk-in door by the dumpster, the southwest overhead receiving door and the southeast truck-loading walk-in door.
- The southwest window in the dry-goods storage area was open and unscreened, and the screen for the window by the southeast walk-in door was damaged and not tightly fitted.

Our lab confirmed rodent evidence collected from various products and from storage areas in your firm.

The above-listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence with each requirement of the federal regulations. Our investigator observed that you have begun an on-going cleanup in your plant, which we acknowledge. He also reported that you have promised to correct other deficiencies that were identified during the inspection. We request that you take prompt action to correct all violations.

Please provide this office, within 15 working days of receipt of this letter, a detailed response stating the actions you plan to take to correct and prevent the recurrence of these objectionable conditions. Provide the time within which the corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action may include seizure and/or injunction.

Your reply should be directed to James T. Karpus, Compliance Officer at the Chicago District Office.

Sincerely,

Raymond V. Mlecko
District Director

Enclosure: Form FDA 483

cc with enclosure: Mr. Larry D. Seibold, Vice President
Mrs. Seibold's Bakery, Inc.
2241 Madison Avenue
Granite City, IL 62040

cc with enclosure: Mr. Michael E. Seibold, Secretary/Treasurer
Mrs. Seibold's Bakery, Inc.
2241 Madison Avenue
Granite City, IL 62040

cc with enclosure: Ms. Carol J. Jones, Office Manager
Mrs. Seibold's Bakery, Inc.
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Granite City, IL 62040